



State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

INSTRUCTIONS FOR FILING AN APPLICATION FOR A CERTIFICATE OF NEED

Applicants unfamiliar with the Tennessee Certificate of Need process are strongly encouraged to contact Health Services and Development Agency (HSDA) staff for a pre-filing conference. Conferences may be held in person or via telephone any business day, 8:00 a.m. – 4:30 p.m. (Central Time). Call 615/741-2364 to set up an appointment.

A certificate of need can only be granted when a project is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, will provide healthcare that meets appropriate quality standards, and it will contribute to the orderly development of adequate and effective health care facilities and/or services in this area. The applicant is responsible for demonstrating that these criteria have been met through its answers to this application and any supplemental questions posed by staff.

Prior to preparation of this application, prospective applications should visit the HSDA website <http://www.tn.gov/hsda/> to consult a variety of resources to include:

- Tennessee Code Annotated § 68-11-1601 et seq.
<http://www.lexisnexis.com/hottopics/tncode/>
 - HSDA Rules and Regulations <http://www.tn.gov/hsda/article/hsda-rules-and-laws>
 - Criteria and Standards for CON <http://www.tn.gov/hsda/article/hsda-criteria-and-standards>
 - Tennessee State Health Plan from the Department of Health, Division of Health Planning <http://www.tn.gov/hsda/article/hsda-state-health-plan> or call 615-532-3161.
 - Health Statistics from the Tennessee Department of Health, Bureau of Policy, Planning, and Assessment including Joint Annual Reports (JAR) for hospitals, home care organizations for home health, and hospice, outpatient diagnostic centers, and ambulatory surgical treatment centers; demographics, vital, and other health statistics by county <http://www.tn.gov/health/section/statistics> or call 615-741-4939.
- Information concerning mental health hospital or non-residential substitution-based treatment center for opiate addiction applications contact the Tennessee Department of Mental Health and Substance Abuse Services <http://www.tn.gov/behavioral-health/topic/licensing> or call 615-532-6500.
- Information concerning intellectual disability institutional habilitation facility applications contact the Tennessee Department of Intellectual and Developmental Disabilities <http://www.tn.gov/didd/topic/office-of-licensure> or call 615-253-6811.
 - "Applicant's Toolbox" <http://www.tn.gov/hsda/topic/applicants-toolbox> includes information and links such as:

- Helpful hints on application layout/hard copy
- Cost per square foot ranges - construction (PDF)
- Charges per procedure - medical equipment (PDF)
- Home health licensed agencies by resident county (PDF)
- Hospice licensed agencies by resident county (PDF)
- Medical equipment location
- Number of procedures - medical equipment - 3 year trend
- Flow Chart of CON Process
- Tennessee Map
- Definitions
- Additional helpful web links

COMMUNICATIONS: All documents for filing a Certificate of Need application must be received at the Health Services and Development Agency during normal business hours (8:00 a.m. - 4:30 p.m. Central Time). The office is located at 502 Deaderick Street, 9th Floor, Nashville, TN 37243. Fax and e-mail transmissions **will not** be considered to be properly filed documentation. In the event that the last appropriate filing date falls on a day the HSDA office is closed, such as Saturday, Sunday, or State holiday, such filing must occur on the preceding business day.

LETTER OF INTENT: The filing of a Letter of Intent shall initiate the CON process. The Letter of Intent must be filed with the Agency between the **first day and the tenth day of the month prior to the beginning of the review cycle** in which the application is to be considered. This allowable filing period is inclusive of both the first day and the tenth day of the month involved. The Letter of Intent must be filed in the form and format as set forth in the application packet.

Any Letter of Intent that fails to include all information requested in the Letter of Intent form, or is not timely filed, will be deemed void. The applicant will be notified in writing. Letters of Intent that are refiled are subject to the same requirements as set out above.

PUBLICATION OF INTENT: Simultaneously with the filing of the Letter of Intent, the Publication of Intent must be published for one day in a newspaper of general circulation in the proposed service area of the project. The Publication of Intent must be in the form and format as set forth in the application packet. The Publication of Intent shall be placed in the Legal Section in a space no smaller than four (4) column inches. Publication must occur between the first day and the tenth day of the month, inclusive.

1. A "newspaper of general circulation" means a publication regularly issued at least as frequently as once a week, having a second-class mailing privilege, includes a Legal Notice Section, being not fewer than four (4) pages, has been published continuously during the immediately preceding one-year period, is published for the dissemination of news of general interest, and is circulated generally in the county in which it is published and in which notice is given.
2. In any county where a "newspaper of general circulation" does not exist, the HSDA's Executive Director is authorized to determine the appropriate publication to receive any required Letter of

Intent. A newspaper which is engaged in the distribution of news of interest to a particular interest group or other limited group of citizens is not a "newspaper of general circulation."

3. In the case of an application for or by a home care organization providing home health or hospice services, the Letter of Intent must be published in each county in which the agency will be licensed or in a regional newspaper which qualifies as a newspaper of general circulation in each county. In those cases where the Publication of Intent is published in more than one newspaper, the earliest date of publication shall be the date of publication for the purpose of determining simultaneous review deadlines and filing the application.

PROOF OF PUBLICATION: Documentation of publication must be filed with the application form. Please submit proof of publication with the application by attaching either the full page of the newspaper in which the notice appeared, with the ***mast and dateline intact***, or a publication affidavit from the newspaper that includes a copy of the publication.

SIMULTANEOUS REVIEW: Those persons desiring a simultaneous review for a Certificate of Need for which a Letter of Intent has been filed must file a Letter of Intent with the Agency and a copy is to be forwarded to the original applicant (as well as any other applicant filing a simultaneous review), and must publish the Letter of Intent simultaneously in a newspaper of general circulation in the same county as the original applicant. The publication of the Letter of Intent by the applicant seeking simultaneous review must be published within ten (10) calendar days after publication by the original applicant.

1. Only those applications filed in accordance with the rules of the Health Services and Development Agency, and upon consideration of the following factors as compared with the proposed project of the original applicant, may be regarded as applications filing for simultaneous review:
 - (A) Similarity of primary service area;
 - (B) Similarity of location;
 - (C) Similarity of facilities; and
 - (D) Similarity of service to be provided.
2. The Executive Director or his/her designee will determine whether applications are to be reviewed simultaneously, pursuant to Agency Rule 0720-10-.03(3).
3. If two (2) or more applications are requesting simultaneous review in accordance with the statute, and rules of the Agency, and one or more of those applications is not deemed complete to enter the review cycle requested, the other applications(s) that is/are deemed complete shall enter the review cycle. The application(s) that is/are not deemed complete to enter the review cycle will not be considered for simultaneous review with the applications(s) deemed complete and entering the review cycle.

FILING INSTRUCTIONS: Failure by the applicant to file an application within five (5) calendar days after publication of the Letter of Intent shall render the Letter of Intent and the application **void**.

For the purpose of filing any information, **the filing date is the actual date of receipt** in the Agency office. These documents, as well as other required documents, must be received as original, signed documents in the Agency office.

- File all documents in triplicate (1 original and 2 copies) on single sided or double-sided, unbound letter size (8½" x 11") paper.
- Do not bind, staple or punch holes in any document.
- *When responding to supplemental questions, type the question and the response.*
- *Answer all questions.* If an item does not apply, please indicate "N/A" (*not applicable*).
- Attach appropriate documentation as an Appendix at the end of the application or supplemental request and reference the applicable item number on the attachment, i.e., Attachment A.1, A.2, etc. For example, an Option to Lease a building should be identified as Attachment A-.6A., and placed before Financial Statements which should be identified as Attachment Section B. Economic Feasibility 6A.
- The last page of the original application, and its two (2) copies, and any supplemental response must be a completed signed and executed affidavit,
- When submitting replacement pages for the original application or previous supplemental responses, the replacement page should include the page number followed by a dash and the letter R(-R). All requested supplemental information must be received by the Agency to allow staff sufficient time for review before the beginning of the review cycle in order to enter that review cycle.
- Responses to supplemental requests should be submitted in their entirety and not in multiple submissions to the maximum extent possible.

Failure to follow the above instructions may result in the application being returned or the review delayed.

FILING FEE:

- The amount of the initial filing fee shall be an amount equal to \$5.75 per \$1,000 of the estimated project cost involved, but in no case shall the fee be less than \$15,000 or more than \$95,000. Checks should be made payable to the Health Services and Development Agency.
- ***FILING FEES*** must be received by the Agency before review of the application will begin. ***Review for completeness will not begin prior to the receipt of the filing fee.***
- Filing Fees are non-refundable, except for denied applications, in which case the applicant shall receive a refund equal to 25% of the examination fee upon request.

COMPLETENESS REVIEW

When the application is received, it will be reviewed for completeness. The application must be consistent with the information given in the Letter of Intent in terms of both project scope and project cost.

- If the application is deemed complete, the Agency will acknowledge that status and notify the applicant as to when the review cycle will begin. “Deemed complete” means that all questions in the application have been answered and all appropriate documentation has been submitted in such a manner that the HSDA can understand the intent and supporting factors of the application. **Deemed complete status shall not be construed as validating the sufficiency of the information provided for the purposes of addressing the criteria under the applicable statutes, the Rules of the Health Services and Development Agency, or the standards set forth in the State Health Plan.**
- If the application is incomplete, requests by Agency staff for supplemental information must be completed by the applicant within sixty (60) calendar days of the initial written request. Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) calendar days which is allowed by the statute. If the requested information is submitted within 60 calendar days of the request, but not by the date specified in the staff’s letter, the application is not void, but will enter the **next** review cycle. If an application is not deemed complete within sixty (60) calendar days after the 1st written notification is given by staff that the application is deemed incomplete, the application shall be deemed void. If the applicant decides to re-submit the application, the applicant shall comply with all procedures as set out by this part and a new filing fee shall accompany the refiled application.

AMENDMENTS OR CHANGES IN AN APPLICATION: As defined by Agency Rule, an application for a Certificate of Need which has been deemed complete **CANNOT** be amended in a substantive way by the applicant during the review cycle. Clerical errors resulting in no substantive change may be corrected.

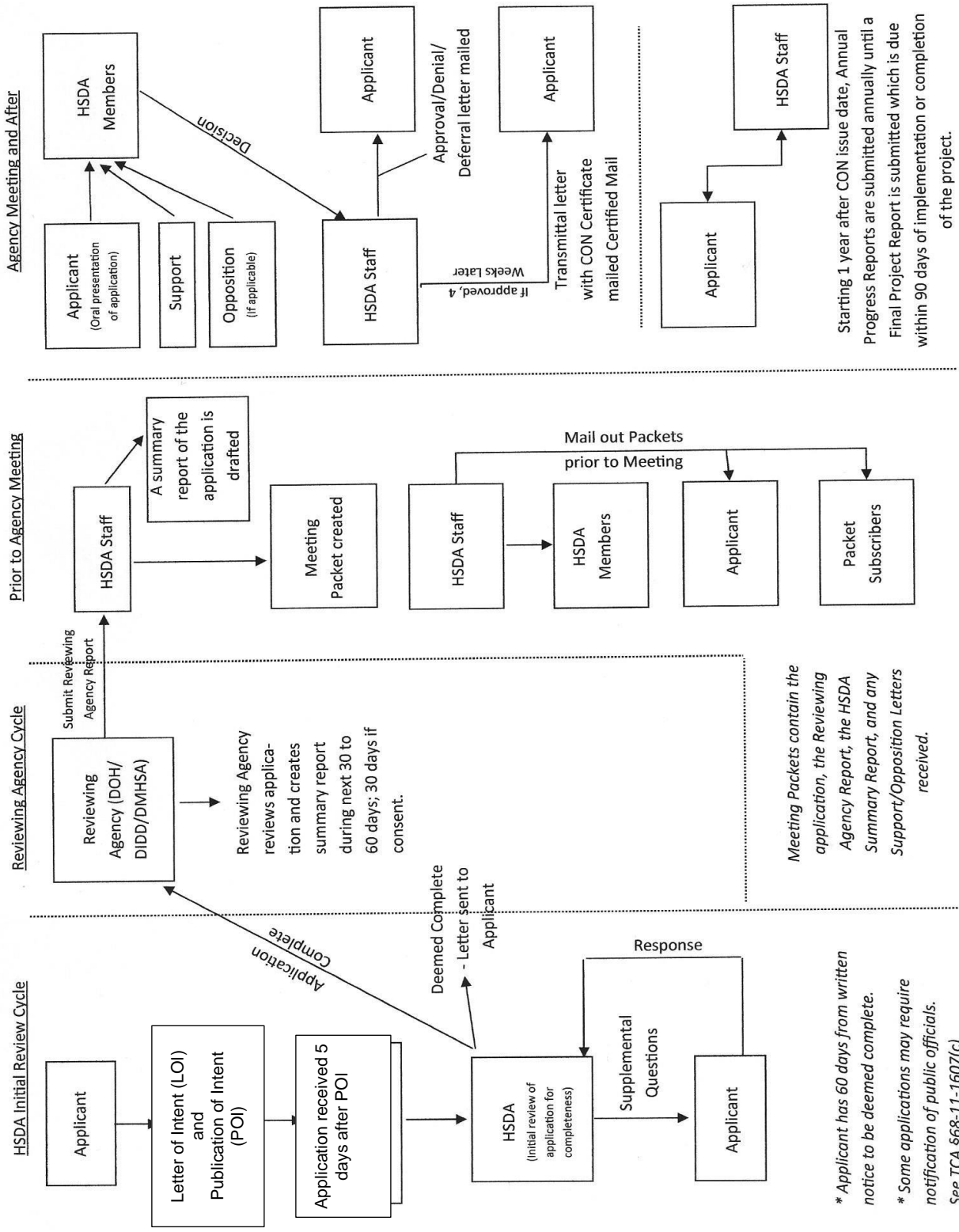
REVIEW CYCLE: Following staff review, the CON application will be forwarded to the appropriate reviewing agency for a 60 calendar day review, unless it is placed on the Consent Calendar, which is a 30 calendar day review. Reviewing agencies include the Department of Health, the Department of Mental Health and Substance Abuse Services, and/or the Department of Intellectual and Developmental Disabilities. The department reviewing the application may contact the applicant to request additional information regarding the application. The applicant should respond to any request for additional information promptly.

WITHDRAWAL OF APPLICATIONS: The applicant may withdraw an application at any time by providing written notification to the Agency. Filing fees are non-refundable when an application is withdrawn.

TIMETABLE FOR CERTIFICATE OF NEED EXPIRATION: A Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; *however*, the Agency may extend a Certificate of Need for a reasonable period upon application and good cause shown. A Certificate of Need shall expire at the end of the extended time period. The decision whether to grant such an extended expiration date is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

For further information concerning the Certificate of Need process, please call the Health Services and Development Agency at 615/741-2364.

CON Process Flow Chart



Meeting Packets contain the application, the Reviewing Agency Report, the HSDA Summary Report, and any Support/Opposition Letters received.

* Applicant has 60 days from written notice to be deemed complete.
 * Some applications may require notification of public officials.
 See TCA §68-11-1607(c)

DEFINITIONS

Agency – Agency and Health Services and Development Agency (HSDA or Agency) is the agency created by T.C.A. §68-11-1601. "Tennessee Health Services and Planning Act of 2002." [Acts 2002, ch. 780, §4.] to administer the certificate of need program and related activities.

Certificate of Need – A permit granted by the health services and development agency to any person for the establishment or modification of a health care institution, facility, or covered health service, at a designated location.

Certificate of Need Criteria – The criteria as defined in the HSDA's Rules 0720-11-.01(1)(2) and (3) General Criteria for Certificate of Need required for approval of a Certificate of Need (on pages 11 and 12).

Conflict of Interest – Any matter before the agency in which the member or employee of the agency has a direct or indirect interest that is in conflict or gives the appearance of conflict with the discharge of the member's or employee's duties;

- (A) "Direct interest" is a pecuniary interest in the persons involved in a matter before the agency. This interest applies to the agency member or employee, the agency member's or employee's relatives or an individual with whom or business in which the member or employee has a pecuniary interest. For the purposes of this part, a relative is a spouse, parent, child, stepparent, stepchild, grandparent, grandchild, brother, sister, half-brother, half-sister, aunt, uncle, niece, or nephew by blood, marriage or adoption; and
- (B) "Indirect interest" is a personal interest in the persons involved in a matter before the agency that is in conflict or gives the appearance of conflict with the discharge of the agency member's or employee's duties.

Consent Calendar – In accordance with T.C.A. §68-11-1601, et seq., as amended by Public Chapter 780--Upon request of the applicant and at the discretion of the Executive Director a project can be placed on the 30-day review cycle for **CONSENT CALENDAR**. The project must meet all the CON criteria and be un-opposed.

Ex parte Communications – Communications with the HSDA's Board Members is in violation of T.C.A. §68-11-1607(d)(1)(2) or §4-5-304.

Facility – Any real property or equipment owned, leased, or used by a health care institution for any purpose, other than as an investment.

Health Care Institution – Any agency, institution, facility or place, whether publicly or privately owned or operated, that provides health services and that is one (1) of the following: nursing home; recuperation center; hospital; ambulatory surgical treatment center; mental health hospital; intellectual disability institutional habilitation facility; home care organization or any category of service provided by a home care organization for which authorization is required under part 2 of this chapter; outpatient diagnostic center; rehabilitation facility; residential hospice; or non-residential substitution-based treatment center for opiate addiction.

The definition of T.C.A. §68-11-1602(7)(B)(i-vi) is provided as follows:

(B) "Health care institution" does not include:

(i) Ground ambulances;

(ii) Homes for the aged;

(iii) Any premises occupied exclusively as the professional practice office of a physician licensed pursuant to title 63, chapter 6, part 2 and title 63, chapter 9, or dentist licensed by the state and controlled by such physician or dentist;

(iv) Administrative office buildings of public agencies related to health care institutions;

(v) Christian Science sanatoriums operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts; or

(vi) A mental health residential treatment facility.

Health Service – Clinically related (i.e., diagnostic or treatment) services and includes those services specified as requiring a certificate of need under §68-11-1607.

Home Care Organization – Any entity licensed as such by the department that is staffed and organized to provide "home health services," or "hospice services" as defined by §68-11-201, to patients in either their regular or temporary place of residence.

Letter of Intent – The form prescribed by the agency which shall require a brief project description, location, estimated project cost, owner of the project and description of services to be performed.

Licensed Beds – The number of beds licensed by the agency having licensing jurisdiction over the facility.

Equipment Registration - §68-11-1607(a); "major medical equipment" does not apply to any equipment not directly related to patient care. Registration is required of certain medical equipment pursuant to Tennessee Code Annotated §68-11-1607(i), which states "*The owners of the following types of equipment shall register such equipment with the health services and development agency: computerized axial tomographers, magnetic resonance imagers, linear accelerators and positron emission tomography.*" "*The survey shall include but not limited to the identification of the equipment and utilization data according to source of payment.*"

Nonresidential Substitution-based Treatment Center for Opiate Addiction – Includes, but is not limited to, stand-alone clinics offering methadone, products containing buprenorphine such as Subutex and Suboxone, or products containing any other formulation designed to treat opiate addiction by preventing symptoms of withdrawal.

Pediatric Patient - a patient who is 14 years of age or younger.

Planning Division – The State Health Planning Division of the Department of Health whose purpose is to develop the state health plan and to conduct other related studies.

Progress Reports – The Health Services and Development Agency Rules require that an Annual Progress Report be submitted each year and a Final Project Report form is to be submitted within ninety (90) days after completion of a project which shall include completion date, final costs, and other relevant information in regards to the project, pursuant to T.C.A. §68-11-1611.

Public Hearings – A fact-finding public hearing on an application held in the area in which the project is to be located per request by interested parties or at the direction of the Executive Director.

Rehabilitation Facility – An inpatient or residential facility that is operated for the primary purpose of assisting in the rehabilitation of physically disabled persons through an integrated program of medical and other services that is provided under professional supervision.

Review Cycle – The timeframe set for the review and initial decision on applications for certificate of need applications that have been deemed complete. The first day of the month is the first day of the review cycle in accordance with T.C.A. §68-11-1601, et seq., as amended by Public Chapter 780, upon the CON application being deemed complete by the Agency.

1. The first sixty (60) calendar days of the cycle are assigned to the reviewing agency, during which time a public hearing may be held on your application. You will be contacted by a representative from HSDA to establish the date, time and place of the hearing should one be requested. At the end of the sixty (60) calendar day period, a written report from the reviewing agency's representative will be forwarded to this office for HSDA review within the thirty (30) calendar day period immediately following. You will receive a copy of their findings.
2. Consent Calendar projects have a thirty (30) calendar day review period.

Reviewing Agency(s) – Department of Health, the Department of Mental Health and Substance Abuse Services, and/or the Department of Intellectual and Developmental Disabilities.

State Health Plan – The plan that is developed by the State Health Planning Division containing clear statements of goals, objectives, criteria and standards for the purpose of guiding the development of health care programs administered or funded by the State of Tennessee through its departments, agencies and programs. The State Health Plan provides guidance to the Tennessee Health Services and Development Agency (HSDA) when issuing Certificates of Need (CON). [Acts 2002, ch. 780, §4.]

RULES
OF
HEALTH SERVICES AND DEVELOPMENT AGENCY

CHAPTER 0720-11
CERTIFICATE OF NEED PROGRAM — GENERAL CRITERIA

TABLE OF CONTENTS

0720-11-.01 General Criteria for Certificate of Need

0720-11-.01 GENERAL CRITERIA FOR CERTIFICATE OF NEED. The Agency will consider the following general criteria in determining whether an application for a certificate of need should be granted:

- (1) Need. The health care needed in the area to be served may be evaluated upon the following factors:
 - (a) The relationship of the proposal to any existing applicable plans;
 - (b) The population served by the proposal;
 - (c) The existing or certified services or institutions in the area;
 - (d) The reasonableness of the service area;
 - (e) The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, TennCare participants, and low-income groups;
 - (f) Comparison of utilization/occupancy trends and services offered by other area providers;
 - (g) The extent to which Medicare, Medicaid, TennCare, medically indigent, charity care patients and low income patients will be served by the project. In determining whether this criteria is met, the Agency shall consider how the applicant has assessed that providers of services which will operate in conjunction with the project will also meet these needs.
- (2) Economic Factors. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors:
 - (a) Whether adequate funds are available to the applicant to complete the project;
 - (b) The reasonableness of the proposed project costs;
 - (c) Anticipated revenue from the proposed project and the impact on existing patient charges;
 - (d) Participation in state/federal revenue programs;
 - (e) Alternatives considered; and
 - (f) The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.
- (3) Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services. The contribution which the proposed project will make to the orderly development of an adequate and effective health care system may be evaluated upon the following factors:

(Rule 0720-11-.01, continued)

- (a) The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, the applicant's proposed TennCare participation, affiliation of the project with health professional schools);
 - (b) The positive or negative effects attributed to duplication or competition;
 - (c) The availability and accessibility of human resources required by the proposal, including consumers and related providers;
 - (d) The quality of the proposed project in relation to applicable governmental or professional standards.
- (4) Applications for Change of Site. When considering a certificate of need application which is limited to a request for a change of site for a proposed new health care institution, The Agency may consider, in addition to the foregoing factors, the following factors:
 - (a) Need. The applicant should show the proposed new site will serve the health care needs in the area to be served at least as well as the original site. The applicant should show that there is some significant legal, financial, or practical need to change to the proposed new site.
 - (b) Economic factors. The applicant should show that the proposed new site would be at least as economically beneficial to the population to be served as the original site.
 - (c) Contribution to the orderly development of health care facilities and/or services. The applicant should address any potential delays that would be caused by the proposed change of site, and show that any such delays are outweighed by the benefit that will be gained from the change of site by the population to be served.
- (5) Certificate of need conditions. In accordance with T.C.A. § 68-11-1609, The Agency, in its discretion, may place such conditions upon a certificate of need it deems appropriate and enforceable to meet the applicable criteria as defined in statute and in these rules.

Authority: T.C.A. §§ 4-5-202, 68-11-1605, and 68-11-1609. Administrative History: Original rule filed August 31, 2005; effective November 14, 2005.